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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
CASELLAS, et al.

Serial No.: 09/831,720

Filed: May 14, 2001

Group Art Unit: 1651

Examiner: B. Ozga

For: USE OF A SUBSTANCE BINDING WITH THE PERIPHERAL BENZODIAZEPIN RECEPTOR FOR TREATING SKIN STRESS

CERTIFICATE UNDER 37 C.F.R. 1.8(a)
I hereby certify that this correspondence is being deposited on the date indicated below with the United States Postal Service as first class mail addressed to:

Commissioner of Patents & Trademarks
Washington, DC 20231.

Name

January 23, 2002
Date

Commissioner of Patents & Trademarks
Washington, D.C. 20231

Dear Sir:

RESPONSE

This is responsive to the Office Action mailed July 25, 2001, setting a three-month period for response.

The October 25, 2001, due date for response is extended three months to January 25, 2002, pursuant to the Request for Extension of Time under 37 CFR 1.136(a) submitted herewith. This response is therefore timely.

Claims 16-41 are in the application. Restriction has been required under 35 U.S.C. § 121 as follows:

Group I: Claims 16-38, drawn to compositions and methods for treating cutaneous stress, classified in class 424, subclass 401.

Group II: Claims 39-41, drawn to microorganisms, classified in class 435, subclass 252.1.

In the telephone conversation of July 19, 2001, with Examiner Ozga, Applicants' undersigned representative provisionally elected Group I, claims 16-18. That election is hereby affirmed. Accordingly, claims 39-41 stand withdrawn from consideration as being drawn to non-elected subject matter, and claims 16-38 are under examination.

Claims 16, 17, 26, 27, and 36 are rejected under 35 U.S.C. § 102(b) as being anticipated by Ormea et al. (J. Ital. Derm., vol. 45, no. 5, pp 325-9, 1970.) The Examiner states that the instant application claims a topical composition for treating cutaneous stress containing as active principle a substance that binds to the peripheral benzodiazepine receptors (PBR) as well as a method of treating cutaneous stress by topical administration of such composition, and urges that Ormea et al. teach alcoholic solutions of Nobrium (a derivative of a benzodiazepine); a topical composition for treating various dermatological disorders (including cutaneous stress) containing as active principle a substance that binds to the peripheral benzodiazepine receptors; and methods for treatment of cutaneous stress which comprise topically administering to a subject in need of such treatment an effective amount of a substance that binds to the peripheral benzodiazepine receptor. Specific reference is made to page 325, fifth paragraph, left [sic, right?] column of the reference.

Applicants' respectfully disagree. The English translation of the Ormea et al. reference (copy herewith) makes clear that the reference nowhere discloses an alcoholic solution of Nobrium, or a topical composition containing a PBR ligand for treating dermatological disorders, nor a method for treating cutaneous stress by topically administering a PBR ligand. The language relied upon by the Examiner at page 325 of the reference is believed to correspond to the third paragraph on page 2 of the translation, wherein it is stated that investigators tested Nobrium's action on the motor and mental spheres of man, both by itself, and in association with alcoholic substances or with a placebo. No mention is made of alcoholic solutions of Nobrium or the topical application thereof. Moreover, it is clear from the language of the second paragraph of the section entitled "Personal Investigations and Their Objectives" at page 3 and from each "Summary of Individual Clinical-Psychological Medical Records" at pages 4-21 that Nobrium was administered orally, frequently in combination with "external therapy" such as packs, creams, pastes or pomades, none of which contained Nobrium. Thus, the Ormea et al. reference neither teaches nor suggests a topical composition containing a substance that binds to the peripheral benzodiazepine receptors for the treatment of cutaneous stress, and cannot possibly anticipate claims 16, 17, 26, 27, and 36. The

rejection is therefore traversed and reconsideration and withdrawal thereof are respectfully requested.

Claims 21 and 22 are rejected under 35 U.S.C. § 102(b) as being anticipated by Levy (A Psychosomatic Approach to the Management of Recalcitrant Dermatoses 4(6), Nov. 1963, 334-7) on the grounds that whereas the instant application claims the active principle as 0.001% to 10% by weight of the total composition weight, Levy teaches 2.5-10 mg of diazepam (p. 336, third paragraph) as the active principle, which is between 0.001-10% of the total weight of the composition.

This rejection of claims 21 and 22 is respectively traversed and reconsideration and withdrawal thereof are requested. The language at page 336 relied upon by the Examiner makes clear that diazepam was administered orally in addition to standard topical therapy, e.g., steroids, tars, dimethisoquin, and calamine lotion. Thus, like the Ormea et al. reference, nothing in the Levy reference either teaches or suggests topical administration of a PBR ligand. Accordingly, the Levy reference cannot possibly anticipate claims 21 and 22.

Claims 16-38 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Ormea et al. in view of Levy and Bloom et al., U.S. Patent 5,614,178. In brief, the Examiner maintains that Ormea et al. and Levy differ from the instant claims in the nature of the specific active ingredient, and that Bloom et al. teach the use of hydroxy acids and retinoic acid in compositions for treating cutaneous stress. The Examiner urges, therefore, that it would have been obvious to substitute the claimed active ingredients for those disclosed in the cited art.

The rejection is traversed and reconsideration thereof is requested. As noted above, neither Ormea et al. nor Levy discloses any topical composition containing a peripheral benzodiazepine receptor ligand or the topical administration thereof. At most, the cited references disclose the conventional oral administration of certain benzodiazpines in addition to the standard topical therapies used in treating dermatological conditions. Nowhere in these references is there any suggestion of the use of PBR ligands in topical preparations for treating cutaneous stress.

As to the Bloom et al. reference, it is acknowledged that hydroxy acids and retinoic acid are used in compositions for treating cutaneous stress. However, there is

nothing in the Bloom et al. reference that would suggest the combination of a hydroxy acid or retinoic acid with a PBR ligand in a topical preparation for treating cutaneous stress, and hence, Bloom et al. adds nothing to Ormea et al. and Levy. Accordingly, it is submitted that the cited references taken either individually or in any combination are incompetent to teach or suggest Applicants' claimed invention and that the rejections based thereon should be withdrawn.

There being no remaining issues, this application is believed in condition for favorable reconsideration and early allowance and such actions are earnestly solicited.

Respectfully submitted,

Dated: January 29, 2002

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